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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,454	11/01/2001	Laura McCulloch	JBP-527	4007

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EXAMINER

JOYNES, ROBERT M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/10/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,454	MCCULLOCH ET AL.	
	Examiner	Art Unit	
	Robert M. Joynes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5,6</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicants' Information Disclosure Statements filed on March 22, 2002 and May 23, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to a method for the prevention of enzymatic dermatitis.

Claims 39-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the “treatment of enzymatic dermatitis”, does not reasonably provide enablement for “prevention of enzymatic dermatitis”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: nature of the invention, breadth of the claims, state of the art, guidance of the specification, predictability of the art, and the working examples. All the factors

have been considered with regard to the claim, with the most relevant factors discussed below.

Nature of the Invention: All rejected claims are drawn to the method of preventing enzymatic dermatitis in a subject with the administration of the composition of the instant claims. The nature of the invention is extremely complex in that it encompasses anticipating the location of the enzymatic dermatitis, how different enzymatic skin irritants will be affected and subsequently administering instant composition such that the subject treated will not have adverse side effects or no effects at all.

Breadth of Claims: The complex nature of the claims is greatly exacerbated by the breadth of the claims. The claim encompasses prevention of multiple complex enzymatic dermatitis in which all enzymatic dermatitis are prevented since the disease may be caused and treated by other means. This may or may not be addressed by the administration of the composition.

State of the Art: The state of the art does not recognize the administration of the instant claimed composition to prevent enzymatic dermatitis due to skin irritants. The state of the art recognizes the treatment of the symptoms of these diseases but not the cure of the disease.

Guidance of the Specification: The guidance given by the specification on how to anticipate enzymatic dermatitis and its location to prevent the disease is absent.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to completely envisioning/anticipating enzymatic dermatitis and

preventing enzymatic dermatitis in a human subject with the administration of the instant composition makes practicing the claimed invention unpredictable in terms of the prevention of the disease.

The Amount of Experimentation Necessary: In order to practice claimed invention, one of ordinary skill in the art would have to first to anticipate enzymatic dermatitis, its location, the effective dosage, duration of treatment, etc. to determine whether or not the instant composition prevents the disease. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art, one of ordinary skill in the art would have to either envision a modification of the variable factors or envision an entirely new combination of the factors, and test the invention again. If unsuccessful again, the whole process would have to be repeated until invention was shown to be successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention.

For these reasons the claim is rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minerath, III et al. (US 6551607 B1) in combination with Hartung et al. (US 5436007).

Minerath teaches methods and compositions for sequestering skin irritants comprising a substrate containing a sequestering agent with an affinity for skin irritants (Col. 3, lines 55-66). The skin irritants are present in nasal secretion, bodily waste or the external environment (Col. 6, lines 45-47). The material suitable for the substrate for the composition includes woven and non-woven webs, fabric, scrims, synthetic fibers and natural fibers (Col. 9, line 14 – Col. 10, line 44). The substrate can contain both hydrophobic and hydrophilic sequestering agents (Col. 6, lines 47- 54). The hydrophilic sequestering agents are chosen from clays, talc, diatomaceous earth, silica, calcium sulfate and the like (Col. 7, lines 24-58; Col. 16, lines 9-40). The hydrophobic sequestering agents are chosen from modifications of the native sequestrants (Col. 7, line 59 – Col. 8, line 14; Col. 16, lines 9-40). The compositions taught can also include lipophilic sequestering agents, humectants, emulsifying surfactants and viscosity enhancers as well as buffering agents, additional active agents, fragrances, dyes, sunscreens, deodorants and combinations thereof (Col. 10, line 54 – Col. 13, line 44).

Minerath does not expressly teach what the exact additional components, such as buffering agents or fragrances, can be in the composition.

Hartung teaches a skin composition that can be delivered to the skin via a wipe or diaper that comprises sodium citrate as a buffering agent (Col. 3, lines 45-59). The wipes or diapers of the reference are used to treat diaper rash, which is caused by bodily waste (Col. 6, lines 28-34). Sodium citrate is one member of the Markush group that defines the peptizing agent.

Neither reference teaches the exact concentration ranges or ratios for components of the composition.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to incorporate sodium citrate into a skin care composition as a buffering agent.

With respect to the claimed concentration ranges, absent a clear showing of criticality, the determination of particular concentrations is within the skill of the ordinary worker as part of the process of normal optimization.

One of ordinary skill in the art would have been motivated to do this to maintain the pH of the composition close to the pH of the skin despite the addition of significant amounts of either alkaline or acidic materials, wherein the buffering system is simple and safe.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703)

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308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
September 7, 2003

THURMAN K. PAGE, J.D.
SUPERVISORY PATENT EXAMINER

